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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,704	08/18/2003	Jose A. Soto	230109	9964

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/641,704

Applicant(s)

SOTO, JOSE A

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/18/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of the Status letters filed on 02/28/05 and 11/15/05.

Claims 1-14 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-9 and 13 are vague and indefinite for reciting the terms "firstly", "secondly" "thirdly" and "fourthly". Use of such terms makes these claims indefinite and confusing. It is further indefinite because it is not clear if these four methods of delivery are options for each user or the user has to go through each and every delivery method.

Claim 6 is indefinite for reciting the term "per time". One of ordinary skill in the art would not have any way of determining what is meant by "per time" in administering the said formulation of the invention.

Claim 7 is indefinite for reciting "and/or". It is not clear if both the methods are used or one or the other. Claim 7 is also indefinite for reciting "up to twenty-four hours or more". Generally "up" implies the most upper limit, thus using "or more" after that is contrary to the general understanding.

Claim 8 is vague and indefinite because the scope of this claim is not clear. Firstly, affecting respiratory tissues and secretions is a very broad scope. Secondly, affecting tissues and secretions are usually done differently. Thirdly, it is not clear what Applicant meant with "as expectorant, mucolytic, decongestant and virucidal". Furthermore it is not clear how secretions are affected by "virucidal", or how tissues or secretions are affected as "decongestant".

Claims 10 and 12 recite the limitation "said bronchial asthma, said acute and chronic bronchitis, and said common cold". There is insufficient antecedent basis for this limitation in the claim. There is NO recitation of the said disorders in the independent claim 8 or claim 9.

Claim 13 is indefinite for reciting "of via" and "said nebulization every two to twelve hours".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 8-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Yvin et al (6,451,352).

Yvin et al teach use of iso-osmotic saline solutions in particular obtained from seawater, to obtain a medicine designed for a treatment preventing and limiting the release of chemical mediators responsible for causing inflammatory phenomena in the human respiratory tracts. To accomplish this, Yvin administers to a patient an effective amount of seawater made iso-osmotic, the seawater being in the form of aerosols or nebulisates wherein the seawater comprises elements such as sodium, calcium, magnesium, etc (see col. 1 and claims 1-2). The said iso-osmotic solution has an osmolarity of from 305 to 315 mOs/kg and a chemical constitution constituting elements such as sodium, potassium, chloride, calcium and magnesium. The raw material is a seawater taken for example at the depth of 5 to 10 meters in an area of strong movement of streams. The said seawater is analyzed, decanted, filtered and stored. Table A discloses typical amounts of each element present in the formulation (col. 2, lines 1-44).

Claims 1-2 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Hassan (6,508,936).

Hasan teaches a desalination process and states that typically sea water will have a cation content on the order of 1.25%-1.75%, of which typically some 700-2000 ppm will be hardness cations, i.e. calcium and magnesium cations, an anion content on the order of 2.2%-2.8%, a pH on the order of 7.9-8.2 (col. 4, lines 35-43). Table 1 shows the typical compositions of Gulf Water and Ocean Seawater. The cations include sodium, potassium, calcium and magnesium and the anions include chloride and sulfate. The amount of each cation or anion in each of the water types are disclosed, in ppm, which appear to be close to the required amounts of the formulation.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Vuong (U.S. 20030205526 A1).

Vuong teaches two stage nanofiltration seawater desalination system and states that over 70 elements are dissolved in seawater. However only six ions make up over 99% by weight of all the dissolved solids in seawater. Sodium and chloride, each of which are in the form of monovalent ions, make up slightly more than 85% of all the dissolved solids in seawater (section [0005]). The data in table 1 shows that the salt concentration of the first permeate is less than 25% of the seawater feed. At about 35000 mg/l salt, the osmotic pressure of the seawater feed vs. first permeate at only about 12% of the salt concentration of the seawater feed, for example is about 315 psi ([0036]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yvin et al (6,451,352)

Yvin et al, discussed above, lacks disclosure on the specific concentration ranges of the elements and dosing periods.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made having the formulations of seawater for treating respiratory disorders such as inflammation caused by chemical mediators in mucus of the respiratory system, to have optimized the concentration ranges of elements needed for treatments and experimented with suitable and conventional dosing periods, with a

reasonable expectations of successfully providing an effective treatment regiment by using a formulation that is free of or low in side effects.

Double Patenting

Claims 1-2 and 14 of this application conflict with claims 1-2 and 14 of Application No. 10/431,721. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer **cannot** overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-2 and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 and 14 of copending Application No. 10/431,421.

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This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-13 of copending Application No. 10/431,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Specifically, the only difference is that claim 3 of the instant Application states the concentration ranges of the elements in millimoles per liter, whereas the concentration ranges of the co-pending Application recites these

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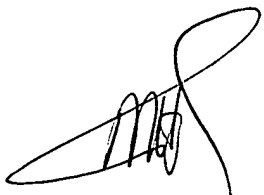
concentration ranges in milligram per liter. However a simple calculation shows that the ranges are interchangeable. In other words they are the same ranges recited in two different measurements. (e.g. 17,550 milligram per liter of sodium is equivalent to 500 millimoles per liter. The atomic mass of sodium is 22.99 grams per mole). Furthermore a method of affecting respiratory tissues and secretions, as Applicant is trying to claim in instant Application, claim 8, is the same as a method of reducing mucus secretion to treat common cold.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
December 02, 2005


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SUPERVISORY PATENT EXAMINER